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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,704	07/25/2001	Stig Jansson	CU-2513 RJS	2557
7590	07/28/2004		EXAMINER WINSTON, RANDALL O	
Thomas F Peterson Ladas & Parry Suite 1200 224 South Michigan Avenue Chicago, IL 60604			ART UNIT 1654	
DATE MAILED: 07/28/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/807,704

Applicant(s)

JANSSON ET AL.

Examiner

Randall Winston

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgement is made of the receipt and entry of the amendment filed on 05/10/2004.

Examiner acknowledges that claims 1-12 have been cancelled and replaced with new claims 13-33.

Claims 13-33 are under examination.

The rejections made under 35 U.S.C. 112 2nd, second paragraph, have been overcome by Applicant's amendment.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 13-29, 32 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Jansson et al. (No. patent application number 1993 3009 or referenced by '309).

Applicant argues that new claims 13-33 are directed to a process, not to a product of the process. Applicant's argument is not found persuasive because new claims 13 and 33's step d separation step is also directed to creating a product and/or composition. Thus, the new claims' objective is the same as the previous examined

claims' objective because the new claims (i.e. claims 13 and 33 step d) are also directed to a process for creating a product.

Applicant further notes that the '309 patent does not inherently disclose a process step for determining the denaturing temperature of the material at issue. Applicant's argument is not found persuasive because new claims 13 and 33 addition of a determining step prior to the thawing step in order not to denature the protein would be an inherent feature within '309 process. On page 9 lines 2-5 of '309, it states that low-temperatures should be used within its process not to denature the proteins. Thus, a determining step would be an inherent feature within '309's process because '309 discloses monitoring its process's temperature by utilizing a low temperature for the purpose of not to denature the protein.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jansson et al ('309) in view of Keyes (US 4,713,335).

As examiner explained in his non-final office action of 01/05/2004, claims 13-29, 32-33, as newly amended, also are rejected under 35 U.S.C. 102(b) for the reasons set

Art Unit: 1654

forth in 01/05/2004. Jansson et al. ('309) do not expressly teach claims 30-31 of the denaturing temperature of the material is determined by visual observation (i.e. claim 30) and/or viscosity measurements (i.e. claim 31).

It would have been obvious to one of ordinary skill in the art at the time the invention was created to modify Jansson et al's process to include visual observation to determine the denaturing temperature of a material because visual observation would be an intrinsic feature within '309 to aid in monitoring the temperature within the process in order not allow the protein to become denatured.

Furthermore, Keyes beneficially teaches (see, e.g. column 5 lines 29-35) that viscosity measurements are used to monitor protein denaturation and/or determine the denaturing temperature within a material.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Jansson et al.'s method to include the disclosure of viscosity measurements are used to monitor protein denaturation and/or determine the denaturing temperature within a material as taught by Keyes' because the combined teachings would create a method of separating elements from a material wherein the elements separated do not contain denatured proteins. Accordingly, the invention as a whole is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Randall Winston whose telephone number is 571-272-0972. The examiner can normally be reached on 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1654

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "Patricia Leith". The signature is fluid and cursive, with a large initial "P" and "L".

PATRICIA LEITH
PRIMARY EXAMINER